Amendments to the Drawings:

The attached sheets of drawings include changes to Figures 6 and 7. These sheets replace the original sheets including Figures 6 and 7.

Attachment: Replacement Sheets

REMARKS

This amendment is submitted in response to the non-final Office Action mailed on November 24, 2004. Claims 1 to 16 are pending in this application.

In the Office Action, the Patent Office objects to informalities in the specification. The specification has been amended to correct the informalities. Accordingly, Applicants respectfully submit that the objection to the specification has been overcome.

In the Office Action, the Patent Office objects to informalities in Figs. 6 and 7. Figs. 6 and 7 have been amended to correct the informalities. Accordingly, Applicants respectfully submit that the objection to the drawings has been overcome.

In the Office Action, the Patent Office objects to informalities in Claim 3. Claim 3 has been amended to correct the informalities. Accordingly, Applicants respectfully submit that the objection to Claim 3 has been overcome.

In the Office Action, Claims 1 and 2 are rejected under 35 U.S.C. §102(b) as being anticipated by the Cell publication to Simonet et al. ("*Cell*"). Claims 1, 3, 6 to 8 and 10 are rejected under 35 U.S.C. §102(b) as being anticipated by PCT Application No. WO 99/53942 to Simonet et al. ("*Simonet*"). Claims 1, 3, 4, 6 to 8, 10 and 11 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,015,938 to Boyle et al. ("*Boyle*"). In response, Applicants have amended Claim 1 to provide an osteoprotegerin obtainable from human or bovine milk or colostrum, wherein the osteoprotegerin includes a glycosylation pattern giving rise to a polypeptide having a molecular weight of approximately 80, 130 and 200 kDa. Claim 2 has been cancelled. Accordingly, Applicants believe these rejections have been overcome for at least the reasons set forth below.

Cell fails to disclose an osteoprotegerin obtainable from human or bovine milk or colostrum, wherein the osteoprotegerin includes a glycosylation pattern giving rise to a polypeptide having a molecular weight of approximately 80, 130 and 200 kDa. In contrast to the claimed invention, *Cell* discloses a recombinant synthesized osteoprotegerin (OPG) that is a disulfide-linked dimer of two 55 kDa monomers. It is known that proteins from different sources can have different glycosylation patterns. Accordingly, the OPG of the present invention obtainable from human or bovine milk or colostrum includes a different glycosylation pattern as

evidenced by the different molecular weights of the polypeptide. As stated in Applicants' specification at, for example, page 5, lines 8-10, the OPG of the present invention exhibits sizes of about 80, 130 and 200 kDa which differ from that obtained by recombinant means (i.e., 55 kDa). Therefore, *Cell* fails to disclose an osteoprotegerin obtainable from human or bovine milk or colostrum, wherein the osteoprotegerin includes a glycosylation pattern giving rise to a polypeptide having a molecular weight of approximately 80, 130 and 200 kDa.

Similarly, *Simonet* and *Boyle* also fail to disclose an osteoprotegerin obtainable from human or bovine milk or colostrum, wherein the osteoprotegerin includes a glycosylation pattern giving rise to a polypeptide having a molecular weight of approximately 80, 130 and 200 kDa. Like *Cell,* both *Simonet* and *Boyle* also disclose a recombinant OPG. *Simonet* pages 18-20 and *Boyle*, column 7, lines 20-34. There is nothing in *Simonet* or *Boyle* to teach or suggest any form of OPG other than OPG obtained by recombinant means exhibiting sizes of 55 kDa. Indeed, *Simonet* incorporates by reference the *Cell* publication disclosing the 55 kDa recombinant OPG as discussed above. Furthermore, *Simonet* discloses mRNA isolated from various tissues expressing OPG include only kidney, liver, placenta and heart, and *Boyle* discloses expression of OPG mRNA only in kidney, liver, placenta, heart, skeletal muscle, lymph node, thymus, spleen and appendix. *Simonet*, page 18, lines 17-19 and *Boyle*, column 4, lines 56-62. Such sources do not suggest an osteoprotegerin obtainable from human or bovine milk or colostrum. Although the OPG disclosed in *Simonet* and *Boyle* have 100% sequence identity to the claimed SEQ ID NO:1, as pointed out by the Patent Office, the fact remains that neither *Simonet* nor *Boyle* disclose an osteoprotegerin obtainable from human or bovine milk or colostrum, wherein the osteoprotegerin includes a glycosylation pattern giving rise to a polypeptide having a molecular weight of approximately 80, 130 and 200 kDa as in the claimed invention.

Accordingly, Applicants respectfully submit that the rejections have been overcome and should be withdrawn.

In the Office Action Claims 5 and 9 are objected to as being dependent on a rejected base claim. Accordingly, Applicants have rewritten Claims 5 and 9 in independent form as new Claims 17 and 18. Therefore, Applicants submit such claims are allowable.

For the foregoing reasons, Applicants respectfully submit that the above-identified patent application is now in a condition for allowance and earnestly solicits reconsideration of same.

Respectfully submitted,

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